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RESEARCH INVOLVING HUMANS: ETHICS, LAW AND REGULATION

VOLUME I

PROFESSOR TRUDO LEMMENS

With the assistance of Paul Miller and Dave Ott

Faculty of Law

University of Toronto

FALL 2002

(FOR INTERNAL USE BY STUDENTS)

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"Opening Statement of the Prosecution, December 9, 1946" and "Judgment and Aftermath" in G. Annas & M. Grodin, eds., *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation* (New York: Oxford University Press, 1992) 67-104. **18**

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Law Commission of Canada, *The Governance of Health Research Involving Human Subjects (HRIHS) – Executive Summary* (Ottawa: Law Commission of Canada, 2000). **257**

U.S. National Bioethics Advisory Commission, "Summary – Protecting Research Participants: A Time for Change," in *Ethical and Policy Issues in Research Involving Human Participants* (Bethesda, MD: National Bioethics Advisory Commission, 2001). **268**

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U.S. National Institutes of Health, *NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects*. Bethesda, MD: NIH, 1998. **472**

P.B. Miller & N.P. Kenny, "Walking the Moral Tightrope: Respecting and Protecting Children in Health-Related Research," (2002) 11 Camb. Q. Healthcare Ethics 217-229. **479**

Tri-Council Working Group, "Section 13 – Research with Collectivities," in *Draft Document: Code of Conduct for Research Involving Humans* (Ottawa: Minister of Supply and Services Canada, 1996) 13-1 - 13-10. **492**

C. Weijer & E.J. Emanuel, "Protecting Communities in Biomedical Research" (2000) 289 *Science* 1142-1144. **503**

U.S. Department of Health and Human Services, Food and Drug Administration, *et al.*, "Guidance for Institutional Review Boards, Clinical Investigators and Sponsors: Exception from Informed Consent Requirements for Emergency Research – Draft Guidance" (Rockville, MD, 30 March 2000). **506**

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K.C. Glass, *et al.*, "Structuring the Review of Human Genetics Protocols Part II: Diagnostic and Screening Studies" (1997) 19:3-4 IRB: A Review of Human Subjects Research 1-13.

K.C. Glass, *et al.*, "Structuring the Review of Human Genetics Protocols Part III: Gene Therapy Studies" (1999) 21 IRB: A Review of Human Subjects Research 1-9.

J.F. Merz, "Is Genetics Research Minimal Risk?" (1996) 18:6 IRB: A Review of Human Subjects Research 7-8.

American Society of Human Genetics, "ASHG Report: Statement of Informed Consent for Genetic Research" (1995) 59 Am. J. Hum. Genet. 471-474.

M. Deschenes, *et al.*, "Human Genetic Research, DNA Banking and Consent: A Question of 'Form'?" (2001) 59 Clin. Genet. 221-239.

L.M. Beskow, *et al.*, "Informed Consent for Population-Based Research Involving Genetics" (2001) 286:18 J. Am. Med. Assoc. 2315-2321.

J.F. Merz, *et al.*, "Protecting subjects' interests in genetics research" (2002) 70:4 Am. J. Hum Genet. 965-71.

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N. Christakis & M.J. Panner, "Existing International Ethical Guidelines for Human Subjects Research: Some Open Questions" (1991) 19 L. Med. & Healthcare 214-221.

R.A. Crouch & J.D. Arras, "AZT Trials and Tribulations" (1998) Nov-Dec Hastings Center Report 26-34.

C. Levine, "Placebos and HIV: Lessons Learned" (1998) Nov-Dec Hastings Center Report 43-48.

XI. Legal Liability

H. Sava, *et al.*, "Legal Liability of Physicians in Medical Research" (1994) 17 Clin. Invest. Med. 148-184.

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P.E. Kalb & K.G. Koehler, "Legal Issues in Scientific Research" (2002) 287:1 J. Am. Med. Assoc. 85-91.

B. Freedman & K.C. Glass, "*Weiss v. Solomon*: A Case Study in Institutional Responsibility for Clinical Research" (1990) 18 L. Med. & Healthcare 395-403.

I. Harvey & R. Chadwick, "Compensation for Harm: the Implications for Medical Research" (1992) 34 Social Sci. Med. 1399-1404.

W.K. Mariner, "Compensation for Research Injuries," in A.C. Mastroianni, *et al.*, eds., *Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies (Vol. 2)* (Washington, DC: National Academy Press, 1994) 113-126.

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Zimmer v. Ringrose (1981) 4 W.W.R. 75

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Stewart v. Cleveland Clinic Foundation 1999 WL 1068225 (Ohio App.8 Dist.)

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